REMARKS

Favorable reconsideration is respectfully requested in view of the foregoing amendments and the following remarks.

I. CLAIM STATUS AND AMENDMENTS

Claims 7, 20, 21, 33, 39, 40, 42, 43 and 47-49 were pending in this application when last examined.

Claims 39, 40, 42, 48 and 49 were rejected.

Claims 7, 20, 21, 33, 43 and 47 were indicated as allowed. Applicants thank Examiner Pryor for the indication of allowable subject matter.

Support for the amendment to claims 39 and 40 can be found in the disclosure, for example, at page 1, line 7, page 3, lines 22-24, page 12, lines 15-18 and at page 79, line 6, to page 80, line 9.

The Specification has been similarly amended at page 7, line 12, to insert subject matter which was inadvertently missed during the preparation of the English translation of the Japanese specification as filed. Support can be found in the disclosure, for example, at page 1, line 7, page 3, lines 22-24, page 12, lines 15-18 and at page 79, line 6, to page 80, line 9.

No new matter has been added.

Claims 7, 20, 21, 33, 39, 40, 42-43 and 47-49 are pending upon entry of this amendment.

II. ENABLEMENT & WRITTEN DESCRIPTION REJECTIONS

On pages 2-5 of the Office Action, claims 39, 40, 42, 48 and 49 were rejected under 35 U.S.C. § 112, first paragraph, on the basis that the Specification lacks enabling support for treatment of the claimed genus of "melatonin related diseases."

Similarly, on pages 5-6 of the Action, claims 39, 40, 42, 48 and 49 were rejected under 35 U.S.C. § 112, first paragraph, on the basis that the Specification lacks written description support for the claimed genus of "melatonin related diseases."

It is respectfully submitted that the present amendment overcomes these rejections.

First, Applicants will discuss the written description rejection. The present amendment overcomes this rejection in that the claims have been amended to limit the "melatonin related diseases" to "biological rhythm disorders" and "somnipathy" and the Specification provides written support for these conditions.

The test for sufficiency of written description is whether the disclosure of the application reasonably conveys to the artisan that the inventor had possession at the time of filing of the subject matter which is claims. See M.P.E.P. § 2163, I, 2100-159, 1st column, 2nd paragraph.

Written support for "biological rhythm disorders" and "somnipathy" can be found throughout the disclosure. For instance, written support can be found in the "Technical Field" and "Background" sections of the disclosure, which discuss melatonin conditions, such as jetlag, biological rhythm disorders, and somnipathy. Support for these conditions can also be found the disclosure, for example, at page 1, line 7, page 3, lines 22-24, and page 12, lines 15-18.

Further written support for the claimed conditions can be found at page 79, line 6, to page 80, line 9 of the disclosure. See for instance, lines 12-16 of page 79, wherein numerous biological rhythm disorders are disclosed, such as sleep-awake rhythm disorder, jet lag, abnormality of physical condition by three change duty, severe depression of a season, genital and neuroendocrine disease, senile dementia, Alzheimer's disease, etc..

In addition, the Specification discusses the relation of binding to a melatonin ML_1 receptor and the recited diseases at page 12, lines 5-18. Also, at page 18, lines 3-6, the Specification discloses the affinity of the compound (I) for the ML_1 receptor.

Therefore, one of skill in the art, upon reading the disclosure and in view of the state of the art, would reasonably believe that Applicants were in possession of the claimed invention. Thus, the written description rejection is untenable and should be withdrawn.

Turning now to the enablement rejection. This rejection was maintained on the basis that: (1) the recitation "melatonin related diseases" is overly broad and there is a lack of correlation between all disease conditions capable of being treated with the present invention, and (2) in view of the unpredictability in the art, the skilled artisan would have to perform an

exhaustive search to determine which diseases can be treated by which compounds of the instant claims. See the top of page 5 of the Action.

It is respectfully submitted that the present amendment overcomes these concerns in that the claims have been amended to limit the "melatonin related diseases" to "biological rhythm disorders" and "somnipathy". As discussed above, the Specification provides support for these conditions. See again, for instance, lines 12-16 of page 79 of the disclosure, wherein numerous biological rhythm disorders are disclosed, such as sleep-awake rhythm disorder, jet lag, abnormality of physical condition by three change duty, severe depression of a season, genital and neuroendocrine disease, senile dementia, Alzheimer's disease, etc..

In view of this amendment and the guidance in the disclosure, it would not require an exhaustive search to determine the disease conditions to be treated by the percutaneous absorption preparations of the present invention.

Furthermore, the Specification provides guidance and numerous working examples demonstrating how to make and use the percutaneous absorption preparations of the present invention.

For instance, Example 1 on page 81 describes the preparation of a percutaneous absorption preparation comprising (S)-N-[2-(1,6,7,8-tetrahydro-2H-indeno [5,4-b]furan-8-yl)ethyl]propionamide (referred to as Compound A). See also, Example 10 on page 85, which describes the preparation of a percutaneous absorption preparation comprising N-[2-(1,6,7,8-tetrahydro-2H-indeno[5,4-b]furan-8-yl)ethyl]acetamide. Accordingly, the Specification provides clear guidance how to make the percutaneous absorption preparations of the present invention.

Also, Example 13 at pages 87-92 describes a rat animal model showing that percutaneous absorption preparations of the present invention enable the active ingredient to be absorbed into the body through a skin contact surface by a convenient administration system, providing a favorable blood-drug-concentration-time profile in which the blood concentration of the active ingredient is kept for 6 to 12 hours. Thus, the Specification provides a working example demonstrating administration of the percutaneous absorption preparations of the present

invention to achieve a favorable blood-drug-concentration-time profile. It is respectfully submitted that the skilled artisan art could extrapolate from this disclosure how to administer such preparations to patients.

In view of this guidance in the disclosure and the knowledge in the art, it is respectfully submitted that the skilled artisan could make the percutaneous absorption preparations of the present invention and then administer these preparations to a patient in need thereof to treat biological rhythm disorders and somnipathy without undue experimentation.

In view of the above, it is respectfully submitted that the Specification provides enabling and written description support for "biological rhythm disorders" and "somnipathy." Accordingly, the enablement and written description rejections of claims 39, 40, 42, 48 and 49 under 35 U.S.C. § 112, first paragraph, are untenable and should be withdrawn.

CONCLUSION

In view of the foregoing amendments and remarks, the present application is in condition for allowance and early notice to that effect is hereby requested.

If the Examiner has any comments or proposals for expediting prosecution, please contact the undersigned attorney at the telephone number below.

Respectfully submitted,

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